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Original article

Assessment of fatigue and dryness in primary Sjögren's syndrome: Brazilian version of "Profile of Fatigue and Discomfort – Sicca Symptoms Inventory (short form) (PROFAD-SSI-SF)"☆

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ABSTRACT

Objective: To perform a cross-cultural adaptation and validation of the Profile of Fatigue and Discomfort – Sicca Symptoms Inventory (short form) (PROFAD-SSI-SF) questionnaire assessing the subjective aspects of the symptoms of primary Sjögren syndrome (pSS), for the Brazilian Portuguese language.

Method: Conceptual, of the item, semantic and operational equivalences were evaluated. The Brazilian version of PROFAD-SSI-SF was administered to 62 women with pSS according to the European-American consensus 2002 to assess measurement equivalence. α-Cronbach was used for internal consistency; intraclass correlation coefficient (ICC) for intraobserver reproducibility; and Spearman correlation coefficient for validity by comparing with Patient Global Assessment (PaGA), EULAR Sjögren's Syndrome Patient Reported Index (ESSPRI), Functional Assessment of Chronic Illness Therapy Fatigue Subscale (FACIT-F) and EuroQOL (EQ-5D).

Results: The internal consistency of PROFAD, SSI and total score was 0.80; 0.78; and 0.87, respectively. The intraobserver reproducibility of total PROFAD was 0.89; of total SSI was 0.86; and total score was 0.89. In terms of validity, PROFAD correlated significantly with PaGA ($r = 0.50$), FACIT-F ($r = 0.59$), ESSPRI ($r = 0.58$) and all domains of EQ-5D, with the exception of Mobility. On the other hand, SSI correlated significantly with PaGA ($r = 0.43$), FACIT-F ($r = 0.57$), ESSPRI ($r = 0.55$) and most domains of EQ-5D. The total score of PROFAD-SSI-SF had a non-statistically significant correlation only with Mobility domain and with 1–100 range of EQ-5D.

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Conclusion: The Portuguese version of PROFAD-SSI-SF proved to be an adaptable, reproducible and valid tool for the Brazilian Portuguese language.

Avaliação da fadiga e da secura na síndrome de Sjögren primária: versão brasileira do "Profile of Fatigue and Discomfort – Sicca Symptoms Inventory (short form) (Profad-SSI-SF)"

Palavras-chave:
Síndrome de Sjögren
Questionário
Estudo de validação
Avaliação
Profad-SSI-SF

RESUMO

Objetivo: Realizar a adaptação transcultural e a validação do Profile of Fatigue and Discomfort – Sicca Symptoms Inventory (short form) (PROFAD-SSI-SF), questionário que avalia os aspectos subjetivos dos sintomas da síndrome de Sjögren primária (SSp), para a língua portuguesa brasileira.

Método: Foi avaliada a equivalência conceitual, de item, semântica e operacional. A versão brasileira do Profad-SSI-SF foi aplicada a 62 mulheres com SSp conforme consenso europeu-americano de 2002 para avaliar a equivalência de mensuração. Foi usado o α-Cronbach para consistência interna; coeficiente de correlação intraclasse (ICC) para reprodutibilidade intraobservador; e coeficiente de correlação de Spearman para validade correlacionado com o *Patient Global Assessment* (PaGA), *EULAR Sjögren's Syndrome Patient Reported Index* (ESSPRI), *Functional Assessment of Chronic Illness Therapy Fatigue Subscale* (FACIT-F) e EuroQOL (EQ-5D).

Resultados: A consistência interna do PROFAD, do SSI e da pontuação total foi de 0,80, 0,78 e 0,87, respectivamente. A reprodutibilidade intraobservador do PROFAD total foi de 0,89; do SSI total de 0,86 e da pontuação total de 0,89. Na validade, o PROFAD apresentou correlação significativa com o PaGA ($r = 0{,}50$), FACIT-F ($r = 0{,}59$), ESSPRI ($r = 0{,}58$) e todos os domínios do EQ-5D, com exceção da mobilidade. Já o SSI apresentou correlação significativa com o PaGA ($r = 0{,}43$), FACIT-F ($r = 0{,}57$), ESSPRI ($r = 0{,}55$) e a maioria dos domínios do EQ-5D. A pontuação total do PROFAD-SSI-SF só não obteve correlação estatisticamente significante com o domínio mobilidade e escala 1 a 100 do EQ-D5.

Conclusão: A versão em português do PROFAD-SSI-SF mostrou ser adaptável, reprodutível e válida para a língua portuguesa brasileira.

Introduction

Primary Sjögren's syndrome (pSS) is a systemic disorder characterized by lymphocytic infiltration and progressive destruction of exocrine glands; however, the inflammatory process can affect any organ. The clinical manifestations can be split into two aspects: (1) benign, but disabling, findings, as dryness, pain and fatigue, affecting the majority of patients and (2) systemic findings that can be potentially severe, affecting about 20–40% of patients.[1] Due to the lack of universally accepted classification criteria, the evaluation of the incidence and prevalence of the disease varies significantly, depending on the criteria used. The prevalence may range from 0.03% to 2.7% of the population.[2] In the Brazilian population, the prevalence, according to the American-European criteria, is 0.17%.[3]

In recent decades, experts established a consensus that it is critical to obtain objective measures of saliva[4] and tear[5] production, as well as to assess dryness and fatigue symptoms, quality of life and activity and disease damage, through valid and reliable assessment instruments,[6–8] both to improve the accuracy of clinical assessment before and after treatment, as to enable conducting clinical trials.

There are few self-assessment instruments focused on the perception of the patient to assess the subjective aspects of his/her symptoms in this disease, as the Profile of Fatigue and Discomfort (PROFAD),[9,10] Sicca Symptoms Inventory (SSI)[10,11] and the most recently tool created by EULAR and already validated for Brazilian Portuguese language, the EULAR Sjögren's Syndrome Patient Reported Index (ESSPRI),[1,12] which is a questionnaire consisting of three domains: fatigue, dryness and pain, assessed by a scale numbered from 0 to 10, with equal weights, and whose final score is the average of the scores of the three domains.

The Profile of Fatigue and Discomfort – Sicca Symptoms Inventory (long form) (PROFAD-SSI-LF) consists of 64 questions scored from 0 to 7 for eight domains: somatic fatigue, mental fatigue, arthralgia, vascular dysfunction, ocular dryness, oral dryness, vaginal dryness and cutaneous dryness.[9,10] However, a long questionnaire can be tiresome for some patients and expensive in clinical trials. Thus, a shorter version was developed and validated: the Profile of Fatigue and Discomfort – Sicca Symptoms Inventory (short form) (PROFAD-SSI-SF),

which consists of 19 questions distributed in the same 8 domains of the long version, having two scores, one for PROFAD and the other for SSI. PROFAD has nine items split into four domains: cutaneous fatigue, mental fatigue, arthralgia and vascular, and SSI has 10 items split into four domains: ocular dryness, oral dryness, vaginal dryness, and cutaneous dryness. In both tools the final score is the sum of its four domains, and varies from 0 to 28.[11] Its advantage is the distinction of fatigue in physical and mental types, as well as in sites of dryness, which do not always appear simultaneously and at the same intensity.

Recent studies in which PROFAD, SSI and ESSPRI were correlated showed that all these tools exhibited significant correlation among themselves and with the patient global assessment for disease activity, thus showing confirmation of construct validity.[13,14] PROFAD was also validated for other rheumatic diseases, such as systemic lupus erythematosus and rheumatoid arthritis, and it has been shown that this tool have moderate to high sensitivity (65–85%) and specificity (55–77%).[9]

Besides the need for validation of this tool, it is critical that it has its psychometric properties tested in several languages and in different populations of patients with pSS. This would allow the realization of cross-cultural studies and of comparisons between national and international studies, thus providing the scientific communication between countries of different languages.[15–17] This study aims to conduct a cross-cultural adaptation and validation of PROFAD-SSI-SF for the Brazilian Portuguese language. An attempt was also made to evaluate the psychometric properties of a total score for the instrument, although the original version did not present it.

Method

This is a cross-sectional observational study approved by the Ethics Committee in Research of the Health Science Center, UFES (Universidade Federal do Espírito Santo), under Opinion number 008/10 and developed in the Sjögren's Syndrome Ambulatory, Rheumatology Outpatient Clinic, Hospital Universitário Cassiano Antonio de Moraes (HUCAM), Vitória, Espírito Santo.

The procedures for the conduction of a cross-cultural adaptation of PROFAD-SSI-SF followed the methodology proposed by Herdman, Fox-Rushby and Badia (1998),[18] which covers six steps: conceptual, of item, semantic, operational, measurement and functional equivalence.

Conceptual, of item, semantic and operational equivalences of PROFAD-SSI-SF were checked at the time of translation and retranslation (back translation), by a committee formed by a rheumatologist and a physiotherapist specialized in Rheumatology, both used in the management of pSS and fluent in English, and an English teacher. The translation of PROFAD-SSI-SF was performed independently by two English language teachers having Portuguese as their native language and aware of the purpose of the study. On retranslation, this version was submitted to a translation into English by two other English teachers having the English as their native language and who were unaware of the original version and of the purpose of the study. To evaluate the semantic equivalence, the Portuguese consensus version was applied to 20 consecutive patients diagnosed with pSS by a rheumatologist used in managing patients with pSS.

Sixty-two patients were selected for the evaluation of measurement equivalence across psychometric properties, according to Streiner and Norman (2008)[19] and Kirshner and Guyatt (1995) methodology[20]; the calculation to composing this sample was based on the use of at least five patients per domain of the instrument.[21] The inclusion criteria were: diagnosis of pSS according to the American-European classification criteria for Sjögren's syndrome,[22] 18 years of age or over, and signing a free and informed consent term. Patients with other concomitant autoimmune diseases were excluded.

Disease activity was subjectively assessed as inactive and active (low, moderate and high activity), according to the onset or worsening of potentially reversible signs and symptoms of disease in the last four weeks, defined by a medical expert, as well as by EULAR Sjögren's Syndrome Disease Activity Index (ESSDAI), whose score ranges from 0 to 123.[17,23] The psychometric properties evaluated were: reliability (intraobserver reliability) and construct validity. The 62 patients underwent clinical evaluation by a physician used in the care of patients with pSS, with completion of the following instruments: PROFAD-SSI-SF, Patient Global Assessment (PaGA), ESSPRI, Functional Assessment of Chronic Illness Therapy Fatigue Subscale (FACIT-F)[24,25] and EuroQOL (EQ-5D)[26] in a single moment (visit 1) and after two days (visit 2).

We opted to replace the self-application of the instrument for a face-to-face interview in the evaluation stages of semantic equivalence and of measurement, considering that this change does not invalidate the use of the questionnaire by self-application[27]; this could be explained by the lack of practice of patients in completing self-administered questionnaires, or by their low level of schooling,[28] and also to avoid the exclusion of illiterate patients or those with eye problems.[29]

α-Cronbach was used in the analysis of internal consistency; for intra-observer reproducibility, the intraclass correlation coefficient (ICC) was used. For the construct validity of the comparison of PROFAD-SSI-SF with PaGA, ESSPRI, FACIT-F and EQ-5D, the Spearman correlation coefficient was used. In all analyzes, the level of significance was accepted as $p \leq 0.05$.

Results

In the phase of conceptual, of item, semantic and operational equivalence, changes in questions 14 and 19 were introduced. In question 14, in the study of semantic equivalence, the literal translation of "blurred vision" would be *visão turva*; however, the word *turva* was replaced by *embaçada*, as this is a term considered more popular. Likewise, the term "swollen salivary glands" in question 19 would mean *inchaço das glândulas salivares*, but *glândulas salivares* is a technical term difficult to understand and locate for the Brazilian population; thus, it was replaced by *região no rosto à frente das orelhas e abaixo do queixo inchados*. There was no question or item misunderstood by more than 15% of the 20 patients in the pre-test. Thus, the final Brazilian language consensus version was obtained.

In the evaluation of measurement equivalence across the psychometric properties, 62 female patients with pSS

Table 1 – Demographic and clinical characteristics of 62 patients with primary Sjögren's syndrome.

Variables	*n* (%) or Mean ± SD
Age (years)	49.4 ± 11.6
Female gender	62 (100)
Time elapsed from the first symptoms (years)	7.2 ± 5.4
Time since diagnosis (years)	3.0 ± 3.3
Interval between symptoms and diagnosis (years)	4.3 ± 4.9
Systemic manifestations in the last visit	29 (46.8)
Inactive disease	29 (46.8)
Active disease	
Low activity	24 (38.7)
Moderate activity	9 (14.5)
ESSDAI	4.95 ± 6.73
Clinical features:	
Objective xerophthalmia (Schirmer I and/or Rose Bengal)	48 (77.4)
Objective xerostomia (Salivary flow/Parotid scintigraphy)	53 (85.5)
Lymphocytic sialadenitis ≥1 focus-score	56 (90.3)
Anti-Ro	27 (43.6)
Anti-La	12 (19.4)
Previous parotid gland swelling	16 (25.8)

SD, standard deviation; ESSDAI, EULAR Sjögren's Syndrome Disease Activity Index.

coming from the Sjögren's Syndrome Ambulatory, Rheumatology Outpatient Clinic HUCAM, were included.

The mean age was 49.4 ± 11.6 years. The duration of illness was 7.2 ± 5.4 years; 46.8% of the patients had some systemic manifestation and 97.9% had been medicated with immunosuppressive agents in some time (Table 1). Most patients (56.41%) had a low level of schooling (<8 years), and 8.06% were illiterate. Most patients exhibited disease activity (53.2%), however, there was a predominance of low activity disease (38.7%). This low activity was confirmed by the mean total score of 4.95 with ESSDAI (0–39), in which 11.3% of patients had a score ≥12. The mean of PROFAD was 18.68 ± 6.23; of SSI was 18.19 ± 6.40; and of the total score of PROFAD-SSI-SF (obtained by averaging PROFAD and SSI results) was 18.34 ± 5.69 (Table 2).

The internal consistency of PROFAD, SSI and of the total score was considered high, and a α-Cronbach corresponding to 0.80; 0.78; and 0.87, respectively, was obtained.

The intraobserver reproducibility of PROFAD was 0.89; of SSI, 0.86; and of the total score was 0.89, showing high reproducibility. The concordance of the questions and domains between the two visits was considered as good to excellent (Table 3).

With respect to the construct validity of PROFAD, statistically significant correlations of domains "Somatic fatigue" and "Arthralgia" with all other variables were obtained. The domain "Mental fatigue" had a statistically significant correlation with PaGA, FACIT-F, ESSPRI (Fatigue, Dryness, and total) and EQ-D5 (Pain/Discomfort and Anxiety/Depression). On the other hand, the domain "Vascular" showed a statistically significant correlation only with FACIT-F and ESSPRI (Pain, Dryness and total). As to PROFAD, a lack of statistically significant correlation only occurred with the domain "Mobility" of EQ-D5 (Table 4). With respect to the construct validity of SSI, the domain "Cutaneous dryness" showed a statistically significant correlation only with FACIT-F; the domain "Vaginal dryness" with FACIT-F, ESSPRI (Fatigue, Dryness, and total) and EQ-D5 (Self care and Usual activities); the domain Ocular dryness with PaGA, FACIT-F and ESSPRI; and the domain "Oral dryness", with all variables. The total score of SSI showed statistically significant correlations with PaGA, FACIT-F, ESSPRI and EQ-D5 (Mobility, Self care and Usual activities) (Table 5). On the other hand, the total score of PROFAD-SSI-SF only lacked a statistically significant correlation with the domain "Mobility" and with 1–100 scale of EQ-D5 (Table 6).

Discussion

The editorial of this journal in 2006[30] highlighted the importance of the translation and validation of assessment tools in rheumatology for the Brazilian Portuguese language, reminding that, with a good-quality instrument available to that effect, the creation of a new instrument requires a greater commitment of time and cost. However, it is not enough that the instrument be simply translated; it is critical an accurate assessment of its translation and cultural adaptation, as well as an evaluation of its measurement (psychometric) properties after the completion of this process, even when such properties have already been demonstrated with the original instrument, as important cultural differences may be present.[30,31]

PROFAD-SSI-SF was originally written in the English language, with questions appropriate to its own culture. Hence, for application of this instrument to our population, we proceeded to a cultural equivalence, so that the tool could actually be adequately interpreted by both patient and evaluator.

Demographic data and clinical characteristics of 62 patients in the stage of measurement equivalence evaluation were similar to those found in other studies of assessment tools for pSS (PROFAD, SSI, PROFAD-SSI-SF and ESSPRI) and their cohorts: prevalence >93% in women, mean age between 47 and 62 years, long disease duration averaging 7.2[1,9–12] years, and mean interval between symptoms and diagnosis of 5 years, which demonstrates a long delay time for diagnosis of this disease, an aspect already reported by others.[32]

The Brazilian version of PROFAD-SSI-SF has demonstrated high internal consistency (0.80 and 0.78), as well as in the validation study of the original version, whose α-Cronbach was 0.99.[11] The intraobserver reproducibility ($r = 0.69–0.85$) also was considered high, similar to the reproducibility of the original PROFAD-LF ($r = 0.67–0.79$), tested 24 h after the first application.[9] The reproducibility of the domains "Ocular dryness" ($r = 0.92$) and "Oral dryness" ($r = 92$) in the study of PROFAD-SSI-SF development was also similar to that in the present study: 0.83 and 0.92, respectively.[33]

In the validation study of PROFAD-LF, the questions in the domain "Somatic fatigue" showed correlation only with the domains "Vitality" of SF-36 ($r = -0.53–0.70$) and "Physical health" of WHOQOL-BREF ($r = -0.62$ and $r = -0.69$),[9] unlike what was observed in the present study, in which that domain showed a statistically significant, although low, correlation with all domains of EQ-5D ($r = 0.28–0.49$).

Table 2 – Descriptive measures of PROFAD-SSI-SF, ESSPRI, EQ-D5, FACIT-F and PaGA.

Variables	Mean (±)	Minimum	Median	Maximum	SD
PROFAD					
Somatic fatigue	5.37	0.50	6	7	1.72
Mental fatigue	5.1	0	6	7	2.17
Arthralgia	5	0	5.5	7	1.98
Vascular	3.21	0	3.5	7	3.03
Total PROFAD	18.68	1.5	18.63	28	6.23
SSI					
Cutaneous dryness	4.79	0	6	7	2.57
Vaginal dryness	4	0	5	7	2.96
Ocular dryness	5.38	0	60	7	1.85
Oral dryness	4.02	0	4.20	7	1.85
Total SSI	18.19	3.53	18.33	28	6.40
PROFAD-SSI-SF, total	18.34	2.52	18.13	27.63	5.69
ESSPRI					
Pain	7.9	0	8	10	2.53
Fatigue	6	0	7.5	10	3.8
Dryness	6.54	0	7	10	2.76
Total	6.81	1.33	7.	10	2.12
EQ-5D					
Mobility	1.66	1	2	2	0.48
Self care	1.35	1	1	2	0.48
Usual activities	1.68	1	2	3	0.57
Pain/Discomfort	2.18	1	2	3	0.53
Anxiety/Depression	2.05	1	2	3	0.66
Scale 1–100	56.73	0	60	100	24.21
FACIT-F	30.73	1	31	52	11.35
PaGA	7.58	2	8	10	2.15

PROFAD, Profile of Fatigue and Discomfort; SSI, Sicca Symptoms Inventory; PROFAD-SSI-SF, Profile of Fatigue and Discomfort – Sicca Symptoms Inventory (short form); PaGA, Patient's Global Assessment; FACIT-F, Functional Assessment of Chronic Illness Therapy Fatigue Subscale; ESSPRI, EULAR Sjögren's Syndrome Patient Reported Index; EQ-5D, EuroQOL; SD, standard deviation.
Scores of instruments: PROFAD, 0–28; SSI, 0–28; PROFAD-SSI-SF total, 0–28; ESSPRI 0–10; EQ-5D, domains – 1–3, range – 0–100; FACIT-F, 0–52; PaGA, 0–10.

Table 3 – Intraobserver reproducibility by questions, domains and total of PROFAD and SSI.

PROFAD		SSI	
Variables	CCI	Variables	CCI
Questions			
Question 1	0.71	Question 10	0.74
Question 2	0.69	Question 11	0.91
Question 3	0.76	Question 12	0.72
Question 4	0.75	Question 13	0.69
Question 5	0.78	Question 14	0.91
Question 6	0.86	Question 15	0.82
Question 7	0.78	Question 16	0.79
Question 8	0.80	Question 17	0.87
Question 9	0.78	Question 18	0.80
		Question 19	0.83
Domains			
Somatic fatigue	0.85	Cutaneous dryness	0.74
Mental fatigue	0.89	Vaginal dryness	0.91
Arthralgia	0.80	Ocular dryness	0.83
Vascular	0.78	Oral dryness	0.92
PROFAD, total	0.89	SSI total	0.86

PROFAD, Profile of Fatigue and Discomfort; SSI, Sicca Symptoms Inventory; CCI, intraclass correlation coefficient.

Table 4 – Spearman correlation of PROFAD with PaGA, FACIT-F, ESSPRI and EQ-5D.

Variables	PROFAD				
	Somatic fatigue	Mental fatigue	Arthralgia	Vascular	Total
PaGA	0.60[a]	0.26[b]	0.66[a]	0.23	0.50[a]
FACIT-F	0.72[a]	0.43[a]	0.51[a]	0.37[b]	0.59[a]
ESSPRI					
Pain	0.43[a]	0.13	0.66[a]	0.33[b]	0.49[a]
Fatigue	0.45[a]	0.50[a]	0.31[b]	0.21	0.46[a]
Dryness	0.43[a]	0.32[b]	0.42[a]	0.25[b]	0.42[a]
Total	0.53[a]	0.46[a]	0.58[a]	0.32[b]	0.58[b]
EQ-5D					
Mobility	0.28[b]	−0.03	0.35[b]	0.06	0.18
Self care	0.49[a]	0.22	0.31[b]	0.01	0.27[b]
Usual activities	0.45[a]	0.12	0.22	0.13	0.28[b]
Pain/Discomfort	0.45[a]	0.29[b]	0.54[a]	0.23	0.43[a]
Anxiety/Depression	0.48[a]	0.33[b]	0.31[b]	0.07	0.29[b]
Scale 1–100	−0.42[a]	−0.06	−0.36[b]	−0.24	−0.31[b]

PROFAD, Profile of Fatigue and Discomfort; PaGA, Patient's Global Assessment; FACIT-F, Functional Assessment of Chronic Illness Therapy Fatigue Subscale; ESSPRI, EULAR Sjögren's Syndrome Patient Reported Index; EQ-5D, EuroQOL.

[a] $P < 0.001$.

[b] $P < 0.05$.

Surprisingly, the domain "Mental fatigue" showed a significant but low correlation with the domain "Anxiety/Depression" of EQ-5D ($r = 0.33$). However, this low correlation was also observed between the questions of the domain "Mental fatigue" of the original PROFAD-LF with the domains "Mental health" of SF-36 ($r = -0.27$ to -0.44), and "Psychological health" of WHOQOL-BREF ($r = -0.32$ to -0.47) and of Hospital Anxiety and Depression Scale (HADS) ($r = -0.34$ to 0.48).[9]

The domain "Arthralgia" of PROFAD-SSI-SF in this study showed a significant correlation with "Mobility" ($r = 0.35$) and "Pain/Discomfort" domains ($r = 0.54$) of EQ-5D. This was also found in the correlation of the questions of "Discomfort" domain of the original PROFAD-LF with "Pain" domain of SF-36 ($r = 0.65$) and "Physical health" domain of WHOQOL-BREF ($r = 0.62$).[9]

In the validation study of ESSPRI, a good correlation between total score of PROFAD ($r = 0.66$) and of SSI ($r = 0.56$) with PaGA[1] was obtained – values similar to those in the present study (0.50 and 0.43, respectively).

As important as the objective measures is the assessment of pSS symptoms focused on patient's perception, both with the aim to determine the clinical improvement in clinical trials, as to observe the progress of patients in

Table 5 – Spearman correlation of SSI with PaGA, FACIT-F, ESSPRI and EQ-5D.

Variables	SSI				
	Cutaneous dryness	Vaginal dryness	Ocular dryness	Oral dryness	Total
PaGA	0.20	0.16	0.59[a]	0.444[a]	0.43[a]
FACIT-F	0.31[b]	0.42[a]	0.43[a]	0.611[a]	0.57[a]
ESSPRI					
Pain	0.08	0.23	0.29[b]	0.33[b]	0.30[b]
Fatigue	0.07	0.34[b]	0.38[b]	0.46[b]	0.41[a]
Dryness	0.22	0.62[a]	0.35[b]	0.55[a]	0.63[a]
Total	0.13	0.49[a]	0.41[a]	0.57[a]	0.55[b]
EQ-5D					
Mobility	0.01	0.19	0.168	0.26[b]	0.27[b]
Self care	0.05	0.35[b]	0.100	0.28[b]	0.29[b]
Usual activities	0.22	0.33[a]	0.025	0.35[b]	0.37[b]
Pain/Discomfort	0.07	0.13	0.232	0.30[b]	0.24
Anxiety/Depression	0.05	0.16	0.197	0.37[b]	0.22
Scale 1–100	0.107	0.02	−0.231	−0.33[b]	−0.11

SSI, Sicca Symptoms Inventory; PaGA, Patient's Global Assessment; FACIT-F, Functional Assessment of Chronic Illness Therapy Fatigue Subscale; ESSPRI, EULAR Sjögren's Syndrome Patient Reported Index; EQ-5D, EuroQOL.

[a] $P < 0.001$.

[b] $P < 0.05$.

Table 6 – Spearman correlation of PROFAD-SSI-SF total with PaGA, FACIT-F, ESSPRI and EQ-5D.

Variables	PROFAD-SSI-SF total
PaGA	0.536[b]
FACIT-F	0.699[b]
ESSPRI	
Pain	0.324[a]
Fatigue	0.423[b]
Dryness	0.441[b]
Total	0.545[b]
EQ-5D	
Mobility	0.242
Self care	0.351[a]
Usual activities	0.421[b]
Pain/Discomfort	0.383[a]
Anxiety/Depression	0.332[a]
Scale 1–100	−0.249

PROFAD-SSI-SF, Profile of Fatigue and Discomfort – Sicca Symptoms Inventory (short form); PaGA, Patient's Global Assessment; FACIT-F, Functional Assessment of Chronic Illness Therapy Fatigue Subscale; ESSPRI, EULAR Sjögren's Syndrome Patient Reported Index; EQ-5D, EuroQOL.

[a] $P < 0.001$.

[b] $P < 0.05$.

clinical practice. Unlike ESSPRI, which has only three questions (domains), diluting relevant groups of symptoms that are not always present together, PROFAD evaluates different aspects of fatigue (somatic and mental) and discomfort (arthralgia and vascular), and SSI evaluates dryness (cutaneous, vaginal dryness, ocular dryness, and oral dryness) separately, and this turns PROFAD-SSI-SF into a more convenient tool to use in clinical practice for monitoring patients' symptoms, and in detailing symptoms in clinical research.

Conclusion

The Brazilian Portuguese version of PROFAD-SSI-SF (Annex 1) proved to be an adaptable, reproducible and valid tool for the Portuguese language and can be used in the Brazilian context.

In addition, the total score obtained by averaging PROFAD and SSI, which is not calculated in the original version, has demonstrated internal consistency, reproducibility and validity.

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Conflicts of interest

The authors declare no conflicts of interest.

Annex 1. Profile of Fatigue and Discomfort – Sicca Symptoms Inventory (short form) (PROFAD-SSI-SF) in Brazilian Portuguese language

Por favor, avalie o quanto os seus sintomas têm estado ruins na pior fase nas últimas duas semanas, assinalando um número de 0 a 7.

1. A maior dificuldade que eu tive nas duas últimas semanas com **necessidade de descanso**, me sentindo **cansado, exausto ou precisando dormir:**

nenhuma necessidade de descansar 0 1 2 3 4 5 6 7 tão ruim quanto você puder imaginar

2. A maior dificuldade que eu tive nas duas últimas semanas **para começar uma atividade, usando muito esforço para fazer as coisas** ou sentindo como se estivesse **"numa batalha":**

nenhuma dificuldade para começar uma atividade 0 1 2 3 4 5 6 7 tão ruim quanto você puder imaginar

3. A maior dificuldade que eu tive nas duas últimas semanas para **continuar uma atividade,** me sentindo **facilmente exausto** ou **sem energia:**

nenhuma dificuldade em continuar uma atividade 0 1 2 3 4 5 6 7 tão ruim quanto você puder imaginar

4. A maior dificuldade que eu tive nas duas últimas semanas com **falta de força nos meus músculos** ou **me sentindo fraco:**

nenhuma falta de força 0 1 2 3 4 5 6 7 tão ruim quanto você puder imaginar

5. A maior dificuldade que eu tive nas duas últimas semanas em **não pensar claramente** ou achando **difícil me concentrar:**

nenhum problema 0 1 2 3 4 5 6 7 tão ruim quanto você puder imaginar

6. A maior dificuldade que eu tive nas duas últimas semanas **esquecendo coisas** ou **cometendo erros:**

nenhum problema 0 1 2 3 4 5 6 7 tão ruim quanto você puder imaginar

7. A maior dificuldade que eu tive nas duas últimas semanas com **desconforto nos meus membros**, como, por exemplo: desconforto ou dor nas grandes juntas (quadril, joelho, ombro) ou nos meus músculos ou dor por todo o corpo:

nenhum problema 0 1 2 3 4 5 6 7 tão ruim quanto você puder imaginar

8. A maior dificuldade que eu tive nas duas últimas semanas com **dor ou inchaço nos dedos ou punhos:**

nenhum problema 0 1 2 3 4 5 6 7 tão ruim quanto você puder imaginar

9. A maior dificuldade que eu tive nas duas últimas semanas com as **mãos desconfortavelmente frias:**

nenhum problema 0 1 2 3 4 5 6 7 tão ruim quanto você puder imaginar

10. A maior dificuldade que eu tive nas duas últimas semanas com pele **seca ou coceira:**

nenhum problema 0 1 2 3 4 5 6 7 tão ruim quanto você puder imaginar

11. A maior dificuldade que eu tive nas duas últimas semanas com **secura vaginal** como, por exemplo: momentos de desconforto durante a relação sexual devido à secura vaginal:

nenhum problema 0 1 2 3 4 5 6 7 tão ruim quanto você puder imaginar

12. A maior dificuldade que eu tive nas duas últimas semanas com **olhos sensíveis** como, por exemplo: sensação de areia, dor, queimação, coceira ou irritação.

nenhum problema 0 1 2 3 4 5 6 7 tão ruim quanto você puder imaginar

13. A maior dificuldade que eu tive nas duas últimas semanas com **irritação nos olhos** como, por exemplo: nos ambientes com fumaça, sentindo desconforto ao vento, no ar condicionado ou lugares com baixa umidade:

nenhum problema 0 1 2 3 4 5 6 7 tão ruim quanto você puder imaginar

14. A maior dificuldade que eu tive nas duas últimas semanas na **visão** (mesmo usando óculos) como, por exemplo, visão embaçada, fraca, com limitação para leitura, para assistir televisão ou dirigir à noite, ver a tela do computador ou a tela do caixa eletrônico de bancos:

nenhum problema 0 1 2 3 4 5 6 7 tão ruim quanto você puder imaginar

15. A maior dificuldade que eu tive nas duas últimas semanas **para me alimentar** como, por exemplo: sentir a boca seca, dificuldade para engolir alimentos, necessidade de ingerir líquidos para engolir os alimentos, alimentos entalados, necessidade de retirar restos de alimentos da boca ou apreciar menos a comida:

nenhum problema 0 1 2 3 4 5 6 7 tão ruim quanto você puder imaginar

16. A maior dificuldade que eu tive nas duas últimas semanas com **garganta ou nariz secos** como, por exemplo: boca seca quando respirando, dificuldade em falar com boca seca, necessidade de ingerir líquido para falar facilmente, sentindo o nariz seco, garganta seca, ou ar condicionado ressecando a minha boca:

nenhum problema 0 1 2 3 4 5 6 7 tão ruim quanto você puder imaginar

17. A maior dificuldade que eu tive nas duas últimas semanas com **mau hálito** como, por exemplo: sentindo que o hálito tinha cheiro ruim, saliva grossa:

nenhum problema 0 1 2 3 4 5 6 7 tão ruim quanto você puder imaginar

18. A maior dificuldade que eu tive nas duas últimas semanas com **necessidade de líquido para molhar a minha boca** como, por exemplo: levar algo para beber na cama, precisar beber algo durante a noite, acordar à noite para urinar, ter necessidade urgente em urinar:

nenhum problema 0 1 2 3 4 5 6 7 tão ruim quanto você puder imaginar

19. A maior dificuldade que eu tive nas duas últimas semanas com **outros problemas na boca**, como, por exemplo: úlceras na boca, regiões no rosto à frente das orelhas e abaixo do queixo inchados, engasgando por causa da secura, mudança em gostos ou sabores, necessidade de ir ao dentista:

nenhum problema	0	1	2	3	4	5	6	7	tão ruim quanto você puder imaginar

SCORE CALCULATION

PROFAD: mean of "somatic fatigue" (1 + 2 + 3 + 4/4) + "mental fatigue" (5 + 6/2) + "arthralgia" (7 + 8/2) + "vascular" (9) domains

SSI: means of "cutaneous dryness" (10) + "vaginal dryness" (11) + "ocular dryness" (12 + 13 + 14/3) + "ocular dryness" (15 + 16 + 17 + 18 + 19/5)

PROFAD-SSI-SF total: mean of PROFAD + SSI

REFERENCES

1. Seror R, Ravaud P, Mariette X, Bootsma H, Theander E, Hansen A, et al. Eular Sjogren's syndrome patient reported index (Esspri): development of a consensus patient index for primary Sjogren's syndrome. Ann Rheum Dis. 2011;70(6):968–72.
2. Patel R, Shahane A. The epidemiology of Sjögren's syndrome. Clin Epidemiol. 2014;6:247–55.
3. Valim V, Pereira AM, Serrano EV, Brito Filho OH, Musso C, Ciconelli RM, et al. Prevalência de síndrome de Sjögren em uma região metropolitana do Brasil. Rev Bras Reumatol. 2013;53(1):24–34.
4. Falcão DP, Mota LMH, Pires AL, Bezerra ACB. Sialometria: aspectos de interesse clínico. Rev Bras Reumatol. 2013;53(6):525–31.
5. Fonseca EC, Arruda GV, Rocha EM. Olho seco: etiopatogenia e tratamento. Arq Bras Oftalmol. 2010;73(2):197–203.
6. Pillemer SR, Smith J, Fox PC, Bowman SJ. Outcome measures for Sjogren's syndrome. J Rheumatol. 2005;32(143):e9.
7. Bowman SJ, Pillemer S, Jonsson R, Asmussen K, Vitali C, Manthorpe R, et al. Revisiting Sjogren's syndrome in the new millennium: perspectives on assessment and outcome measures. Rheumatology (Oxford). 2001;40(1180):e8.
8. Seror R, Bootsma H, Bowman SJ, Dörner T, Gottenberg JE, Mariette X, et al. Outcome measures for primary Sjögren's syndrome. J Autoimmun. 2012;39(1–2):97–102.
9. Bowman SJ, Booth DA, Platts RG. Measurement of fatigue and discomfort in primary Sjogren's syndrome using a new questionnaire tool. Rheumatology (Oxford). 2004;43(758):e64.
10. Bowman SJ, Booth DA, Platts RG, Field A, Rostron J. Validation of the Sicca symptoms inventory for clinical studies of Sjogren's syndrome. J Rheumatol. 2003;30(1259):e66.
11. Bowman SJ, Hamburger J, Richards A, Barry RJ, Rauz S. Patient-reported outcomes in primary Sjögren's syndrome: comparison of the long and short versions of the Profile of Fatigue and Discomfort – Sicca Symptoms Inventory. Rheumatology. 2009;48:140–3.
12. Paganotti MA, Miyamoto ST, Serrano EV, Altoe R, Valim V. Adaptação transcultural e avaliação das propriedades psicométricas do Eular Sjogren's Syndrome Patient Reported Index (Esspri). In: XXIX Congresso Brasileiro de Reumatologia, Vitória (ES). Rev Bras Reumatol. 2012;52:23–4.
13. Ng W-F, Bowman S, Griffiths B. The UKPSSR study group relationship between disease activity of primary Sjogren's syndrome and patient reported outcome e data from an interim analysis of the UK primary Sjögren's syndrome registry. Ann Rheum Dis. 2011;70:510.
14. Seror R, Ravaud P, Bowman SJ, Mariette X. Patients' complaints depend on systemic status in patient with primary Sjögren's syndrome. Ann Rheum Dis. 2010;69:569.
15. Giusti E, Befi-lopes DM. Tradução e adaptação transcultural de instrumentos estrangeiros para o português brasileiro. Pró-Fono R Atual Cient. 2008;20(3):207–10.
16. Machado RIL, Souto LM, Freire EAM. Tradução, adaptação cultural e validação para a língua portuguesa (Brasil) do Systemic Sclerosis Questionnaire (SySQ). Rev Bras Reumatol. 2014;54(2):95–101.
17. Serrano EV, Valim V, Miyamoto ST, Altoe R, Paganotti MA, Cade NV. Adaptação transcultural do Eular Sjögren's Syndrome Disease Activity Index (Essdai) para a língua portuguesa. Rev Bras Reumatol. 2013;53(6):483–93.
18. Herdman M, Fox-Rushby J, Badia X. A model of equivalence in the cultural adaptation of HRQoL instruments: the universalist approach. Qual Life Res. 1998;7:323–5.
19. Streiner DL, Norman GR. Health measurement scales: a practical guide to their development and use. 4th ed. Oxford: Oxford University Press; 2008.
20. Kirshner B, Guyatt G. A methodological framework for assessing health indices. J Chronic Dis. 1985;38(1):27–36.
21. Hair JF, Anderson RE, Tatham RL, Black WC. Factor analysis. In: Multivariate data analysis. 4th ed. New Jersey: Prentice Hall; 1995.
22. Vitali C, Bombardieri, Jonsson R, Moutsopoulos HM, Alexander EL, Carsons SE, et al. Classification criteria for Sjögren's syndrome: a revised version of the European criteria proposed by the American-European Consensus Group. Ann Rheum Dis. 2002;61:554–8.
23. Seror R, Ravaud P, Bowman SJ, Baron G, Tzioufas A, Theander E, et al. Eular Sjogren's syndrome disease activity index: development of a consensus systemic disease activity index for primary Sjogren's syndrome. Ann Rheum Dis. 2010;69(6):1103–9.
24. Webster K, Cella D, Yost K. The Functional Assessment of Chronic Illness Therapy (FACIT) measurement system: properties, applications, and interpretation. Health Qual Life Outcomes. 2003;1:79.
25. Webster K, Odom L, Peterman A, Lent L, Cella D. The Functional Assessment of Chronic Illness Therapy (FACIT) measurement system: validation of version 4 of the core questionnaire. Qual Life Res. 1999;8(7):604.
26. The EuroQol, Group. EuroQol – a new facility for the measurement of health-related quality of life. Health Policy. 1990;16(3):199–208.
27. Moraes CL, Hasselmann MH, Reichenheim ME. Portuguese-language cross-cultural adaptation of the Revised Conflict Tactics Scales (CTS2), an instrument used to identify violence in couples, vol. 18. Cad Saúde Pública/Ministério da Saúde, Fundação Oswaldo Cruz, Escola Nacional de Saúde Pública; 2002. p. 163–76.
28. Orfale AG, Araújo PMP, Ferraz MB, Natour J. Translation into Brazilian Portuguese, cultural adaptation and evaluation of the reliability of The Disabilities of the Arm, Shoulder and Hand questionnaire. Braz J Med Biol Res. 2005;38: 293–302.
29. Oku EC, Andrade AP, Stadiniky SP, Carrera EF, Tellini GG. Tradução e adaptação cultural do Modified University of California at Los Angeles Shoulder Rating Scale para a língua portuguesa. Rev Bras Reumatol. 2006;46:246–52.

30. Lage LV, Levy RA, Ciconelli RM. Instrumentos de avaliação em reumatologia: importância de sua tradução e validação em nosso idioma. Rev Bras Reumatol. 2006;46:237.
31. Guillemin F, Bombardier C, Beaton D. Cross-cultural adaptation of health-related quality of life measures: literature review and proposed guidelines. J Clin Epidemiol. 1993;46:1417–32.
32. Manthorpe R, Asmussen K, Oxholm P. Primary Sjogren's syndrome: diagnostic criteria, clinical features, and disease activity. J Rheumatol. 1997;24 Suppl.:8–11.
33. Bowman SJ, Booth DA, Platts RG. Profile of fatigue and discomfort and Sicca Symptoms Inventory manual; 2002. Supplied by the authors.